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Docket No: PR 60 397W
Attorney: VGC
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Due Date:
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	28 FEB 2005
Applicant's or agent's file reference PR60397WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/29748	10 September 2004 (10.09.2004)	26 September 2003 (26.09.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 31/42 and US Cl.: 514/378

Applicant

SMITHKLINE BEECHAM CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Raymond J Henley III Telephone No. 571-272-0600

Form PCT/ISA/237 (cover sheet) (January 2004)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/29748

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/29748

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-12	YES
	Claims NONE	NO
Inventive step (IS)	Claims 1-12	YES
	Claims NONE	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-12 meet the criteria under PCT Article 33(2) for novelty because the cited reference fails to teach the presently claimed method for treating, reducing or preventing development of liver fibrosis comprising administering to a mammalian subject in need thereof a therapeutically effective amount of an FXR agonist.

Claims 1-12 meet the criteria under PCT Article 33(3) for inventive step because the cited reference fails to teach or suggest the presently claimed method for treating, reducing or preventing development of liver fibrosis comprising administering to a mammalian subject in need thereof a therapeutically effective amount of an FXR agonist.

Claims 1-12 meet the criteria under PCT Article 33(4) because the presently claimed method for treating, reducing or preventing development of liver fibrosis comprising administering to a mammalian subject in need thereof a therapeutically effective amount of an FXR agonist would have applicability in the medical industry.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 4-6, 8, 10 and 12 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because of the following reasons.

The objective truth of the statement that liver fibrosis can be prevented is doubted because the term "preventing" is synonymous with the term "curing" and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as a liver fibrosis, the description, which lacks an objective showing that liver fibrosis can actually be prevented, is viewed as lacking an enabling disclosure of the same.

Claims 9-12 are objected to under PCT Rule 66.2(a)(v) and PCT Article 6 because the claims are indefinite.

The term "small" in claims 9-10, i.e., "a synthetic small molecule organic compound", is a relative term which renders the claims indefinite. The term "small" is not defined by the claim, the description does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "small" would invite subjective interpretations of whether a particular molecule was included in or excluded from the present claims and such interpretation is inconsistent with the requirements for definiteness as set forth in the above cited PCT rule and article.